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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,631	06/27/2003	F. Chris Minion	08411-035001	5135

26191 7590 09/25/2006

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,631	MINION ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *6-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election

1. Applicant's amendment filed on 7/5/06 is acknowledged.

Status of Claims

2. Claims 1 and 2 have been amended.

New claims 28 and 29 have been added and are included in the elected invention.

Claims 1-5 and 27-29 are under examination.

Claims 6-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC 112 maintained

3. The written description rejection for claims 1-5 , 27 is maintained as set forth in the previous office action. The same rejection applies for the newly added claims 28-29.Therefore , claims 1-5 and 27-29 stand rejected.

Applicants refer the Examiner to Capon et al. v. Eshhar e Dudas (418 F.3d 1349, 76 USPQ2d 1078 (Fed. Circ. 2005)) and Invitrogen Corp. v. Clontech, Laboratories, Inc. (429 F.3d 1052 (Fed. Circ. 2005)) to support the written description of the instantly claimed invention and particularly states that neither Capon nor Invitrogen are inconsistent with the earlier Fiers and Amgen cases cited by the Examiner.

The arguments have been considered but have not been found persuasive because Applicant has not demonstrated a nexus between the fact pattern in the instant specification and that in *Capon et al .v. Eshhar.* In particular, although Applicant points to the ruling wherein if the sequence information is known in the prior art, it is unnecessary to provide it new, although the specification provides SEQ ID NO:8, the sequences of the claimed variants (i.e., polypeptides less than the full length) are not in fact known as claimed. Given the above,

although Applicant suggests a similarity between the claims of the instant invention and the claims reviewed in the Eshhar and Clontech case, Examiner fails to see any similarity between the two cases. For example: unlike the known structure of the Eshhar claims, the structure of the broadly claimed variants is unknown because no structure function relationship has been identified. Similarly, Applicant has not demonstrated a nexus between the fact pattern in the instant specification and that of *Invitrogen Corp.v. Clontech* as the claims of present invention are not drawn to genes encoding reverse transcriptase having substantially reduced Rnase H activity.

Applicant states that the claims explicitly require that the polypeptide be immunogenic and the specification provides a significant amount of written description regarding making, identifying, and using immunogenic polypeptides(pages 17 -22 and throughout the Examples). In addition to describing the actual sequence of the polypeptide from which the claimed immunogenic polypeptides can be obtained (i.e., SEQ ID NO: 8), the specification describes an immunogenic polypeptide functionally (see, for example, page 11, lines 17-19) and provides a significant amount of disclosure regarding using the claimed immunogenic polypeptides for either or both a vaccine or in a method of detecting infected swine. (pages 17-22 as well as throughout the Examples). Further , the specification also provides a significant a amount of written description for immunogenic fragments and variants (e.g., mutants) of SEQ ID NO:8. (page 9, lines 6-9; page 10, lines 19-26; page 11, lines 20-21; page 16, lines 18- 22; page 21, lines 19-20; and page 37, lines 24-25 and 29). In addition, fragments generated from enzymatic cleavage of a larger polypeptide are described throughout the specification(page 29, lines 3-7; page 30, lines 8-11; page 31, lines 19-25; and page 48, lines 4).Based on the maturity of the science and the predictability of the aspects at issue, Applicants have met the written description requirement for the claimed polypeptides and fragments thereof.

Applicant's arguments filed on 7/05/06 have been fully considered but they are not deemed to be persuasive because the examiner could not find written description support for the claimed invention in the specification as stated by the applicant. While immunogenic polypeptide consisting of at least eight or 12 consecutive residues of SEQ.ID.NO:8 or are fully disclosed by the current specification, however, the instant specification does not provide an adequate written description of an isolated immunogenic polypeptide comprising at least eight or 12 consecutive residues of SEQ.ID.NO:8 . Further, the claimed immunogenic polypeptide do not satisfy the written description guidelines because an isolated immunogenic polypeptide comprising (open language) at least 8 amino acids plus unlimited and unknown amino acids and an isolated immunogenic polypeptide comprising 12 amino acids 2 plus unlimited and unknown amino acids would result in an unknown fragments without any structure and other identifying characteristics such as function. Thus, immunogenic polypeptide as claimed are broader than SEQ.ID.NO: 8 . Further, it is noted that that although applicant argues that the claimed invention is required to be immunogenic , it is noted for applicant's information that immunogenicity/immunoreactivity is not considered to be a function of the polypeptide, rather, it is a physical property of the polypeptide. A physical property is a basic or essential attribute shared by all members of class as defined by http://dict.die.net/property. Or a property used to characterize physical objects as defined by http://wordnet.princeton.edu/perl/webwn. In the instant case, the basic or essential attribute shared by all members of the claimed class, the property used to characterize these molecules is that all polypeptides are immunogenic. In point of fact, the only molecule that has a function drawn to the immunogenicity of a polypeptide , is the immune system molecule that binds to it. Thus , as previously set forth, the specification provides no nexus between any structure and function of the broadly claimed variants. This is especially true given that immunogenicity is not a function of the claimed polypeptide. Although

the specification states that the claimed molecules are part of the invention and make reference to a potential method for making it. This does not satisfy the requirements as previously set forth.

Applicant argues that the specification provides a significant amount of written description for immunogenic fragments and variants and points to at least ten cites in the specification

The argument has been considered but has not been found persuasive because a review of the cites does not reveal information that is adequate to meet the written description requirement of 35 USC 112, first paragraph for the reasons of record.

4. The scope of enablement rejection for claims 1-5 and 27 is maintained as set forth in the previous office action. The same rejection applies for the newly added claims 28-29. Therefore , claims 1-5 and 27-29 stand rejected.

Applicant states that enablement "is not precluded even if some experimentation is necessary, although some experimentation needed must not be unduly extensive and cites Hybritech Inc. v. Monoclonal Antibodies, Inc. In addition, not only are polypeptides comprising 8 or 12 residues of SEQ .ID. NO:8 are enabled, polypeptides varying in sequence from SEQ ID NO:8 are also enabled for the same reasons. Making variants is routine in the art with currently available equipment and procedures, many of which are automated, hundred and thousands of different polypeptides including variants can be readily and rapidly screened specific binding affinity to an antibody without undue experimentation.

Applicant's arguments filed on 7/05/06 have been fully considered but they are not deemed to be persuasive because the specification discloses an isolated polypeptide comprising the amino acid as set forth in the SEQ.ID.NO:8 and an immunogenic polypeptide consisting of 8 or 12 amino acid of SEQ.ID.NO:8 Although applicant argues that it is routine in

the art to generate fragments and to determine whether or not those fragments are immunogenic and bind to an antibody , the requirements of 35 USC 112 first paragraph are drawn to teaching of how to make and use the claimed invention and are not drawn to screening of molecules in order to determine whether or not the invention would function as claimed. Further, the screening assays suggested by applicant do not enable the claimed invention because the court found in *Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004 that screening assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the claimed chemical invention. It is clear from the Applicant's argument suggesting screening that the specification does provide the necessary guidance to the practitioner to enable the making of the broadly claimed invention, that is the ability to predictably distinguish between those molecules that are immunogenic from those that are not . Since the making of the broadly claimed invention is not enabled, one would not know how to use the broadly claimed invention. Therefore, it is appropriate to maintain the rejection.

Claim Rejections - 35 USC 102 maintained

5. The rejection of claims 1-5 and 27 under 35 U.S.C. 102(b) as being anticipated by database Uniprot_03, Accession number Q9KGX7 or. Q9KGX9 is maintained as set forth in the previous office action.

Applicant argues that the cited art does not disclose the carboxy terminus of the amino acid sequence disclosed in Q9KGX7, which corresponds to the amino terminus of the claimed SEQ ID NO:8, was ever purified. As drawn to claims 1-5, 27, the argument has been considered but has not been found persuasive because applicant is arguing limitations not recited in the claims as currently constituted.

6. The rejection of claims 1-5 and 27under 35 U.S.C. 102(b) as being anticipated by Zhang et al Infect. Immun., Mar 1995, 1013-1019, Vol 63, No. 3 is maintained as set forth in the

previous office action. The same rejection applies for the newly added claims 28-29. Therefore , claims 1-5 and 27-29 stand rejected.

Applicant states that the pending claims are directed toward a "purified" and Zhang et al's protein is certainly not "purified" as the pending claims require.

Applicant's arguments filed on 7/05/06 have been fully considered but they are not deemed to be persuasive because the reference on page 1014, right column, 2nd paragraph indicates that the protein is purified by affinity chromatography using monoclonal antibody. Therefore, this rejection is maintained.

New Rejections Based on Amendment

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 28-29 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Claims 28-29 are rejected because the limitation of "at least eight consecutive residues from the carboxy terminal 1319 res of SEQ ID NO: 8" and "at least eight consecutive residues between residues 561 and 1879 of SEQ. ID NO:8" have no clear support in the specification and the claims as originally filed. In the response filed on 6/30/06 applicant pointed to several pages in the specification . However, upon review of the cited pages, there is nothing in the specification to suggest the specific recitation of "the carboxy terminal 1319 res of SEQ ID NO: 8" and "

residues 561 and 1879 of SEQ. ID NO:8" as claimed. The subject matter claimed in claims 28-29 broadens the scope of the invention as originally disclosed in the specification.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert Navarro can be reached on (571) 272-0861. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER